UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

Scott Powers, individually, as Representative of the Estate of Erika Zak, and as the natural guardian of L.P., a minor,

Civil Action No.: 1:20-cv-02625 (LGS)

Plaintiff,

VS.

Constantinos Sofocleous and Memorial Sloan Kettering Cancer Center,

Defendants.

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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POINT I: Plaintiff's Response 56.1 Statement is improper

Plaintiff's Response 56.1 Statement (Doc. 235-1 ("56.1")) violates Local Rule 56.1 and FRCP 56. Plaintiff's responses are not "short and concise" and are replete with lengthy and impermissible arguments.¹ Some responses are redundant and unresponsive.² In others responses, Plaintiff did not set forth a genuine dispute of Defendants' stated fact;³ did not support his response by the evidence cited,⁴ cited to evidence not included in his exhibits,⁵ or cited to inadmissible evidence.⁶ Several responses contain statements unaccompanied by a citation to evidence amounting to impermissible attorney statements.⁷ Accordingly, the Court must strike Plaintiff's improper responses and deem each statement of fact admitted for purposes of the Defendants' motion for summary judgment.⁸

POINT II: Plaintiff's medical malpractice claims fail

Plaintiff's lack of "best judgment" argument does not relieve him of his burden of demonstrating a departure from the standard of care to support his claims alleged. In the decision Plaintiff relies on, <u>Nestorowich v. Ricotta</u>, 97 N.Y.2d 393, 401, 767 N.E.2d 125, 130 (N.Y. 2002), the Court of Appeals reaffirmed the requirement of establishing a deviation: "...the proper standard [is] whether defendant deviated from accepted medical practice."

F.2d 736, 740 (2d Cir. 1987) ("Where such evidence is not proffered, the defendant is entitled to judgment").

 $[\]begin{array}{l} ^{1} \underline{\text{See}} \ 56.1, \P 14; \P 16; \P 46; \P 49; \P 55; \P 56; \P \P 58-61; \P \P 68-71; \P \P 73-79; \P 82; \P 83; \P 86; \P \P 88-90; \P 94; \P 99; \P \P 106-108; \P 111-115; \P 118; \P 124; \P 133; \P 138; \P 146; \P 151; \P 157; \P 159; \P 175; \P 181; \P 182; \P 195; \P 196; \P 206; \P 207; \P 211; \P 213; \P 196-219. \end{array}$

² Id., ¶¶49-51; ¶53; ¶55; ¶80; ¶87; ¶95; ¶124; ¶129 and ¶¶200-203. No response to ¶5, ¶28 or ¶44.

⁴ <u>Id.</u>, ¶9; ¶13; ¶14; ¶16; ¶46; ¶55; ¶59; ¶61; ¶68; ¶70; ¶75; ¶77; ¶78; ¶83; ¶84; ¶90; ¶99; ¶¶105-109; ¶113; ¶118; ¶124; ¶148; ¶151; ¶154; ¶160; ¶175; ¶181; ¶182; ¶¶187-189; ¶195; ¶196; ¶204; ¶209; ¶213; ¶215; ¶219 and ¶220.

⁵ <u>See</u> 56.1, ¶59; ¶61; ¶69; ¶96; ¶105; ¶144; ¶146; ¶196 and ¶199.

⁶ <u>See</u> 56.1, ¶¶94-98; ¶106; ¶113 and ¶182.

⁷ <u>Id.</u>, ¶31; ¶38; ¶43; ¶49; ¶55; ¶58; ¶59; ¶68, ¶70; ¶74; ¶75; ¶77;¶83; ¶84; ¶86; ¶88; ¶90; ¶94; ¶99; ¶108; ¶112; ¶114; ¶115; ¶118; ¶121; ¶124; ¶133; ¶151; ¶156; ¶182; ¶196; ¶199; ¶¶206-209; ¶211; ¶215 and ¶219.

⁸ <u>See Giannullo v. City of N.Y.</u>, 322 F.3d 139, 140 (2d Cir. 2003) (citations omitted) (Where an opposing party "fails to controvert a fact so set forth in the moving party's Rule 56.1 statement, that fact will be deemed admitted.).

⁹ <u>See</u> 56.1, ¶209 (did not dispute that Dr. Navuluri's report contained no opinion that Dr. Sofocleous departed from the standard of care; his contentions therein are insufficient to create an issue of fact). <u>Sitts v. United States</u>, 811

A) Plaintiff failed to provide expert testimony that the standard of care required that Ms. Zak's case be presented to a multidisciplinary tumor board ("MDTB").

It is undisputed that Dr. Kemeny (oncologist) had a discussion with Dr. Sofocleous (interventional radiologist) about whether he thought ablation was appropriate before she referred Ms. Zak to Dr. Sofocleous on March 22, 2017. (56.1, ¶72). Plaintiff failed to controvert the expert opinion that "[i]t is standard for an oncologist to refer a patient directly to an interventional radiologist for advisability of local therapy, such as ablation." (56.1, ¶69). Plaintiff argues that his expert, Dr. Navuluri, opined in his report "that Drs. Sofocleous and Kemeny should have presented this case to a multidisciplinary tumor board." (Plt's MOL in Opposition ("Opp.") p. 14). However, there is no such opinion contained therein. ¹⁰ In reality. Dr. Navuluri opined that a patient "may be referred directly to IR [interventional radiologist] by another provider after an off-line discussion has occurred" (Doc. 230-18, p. 3), which is what occurred here. (56.1, ¶¶64, 66, 72 and 93). Dr. Navuluri opined "I don't believe tumor board would necessarily be ["]designed["] a 'standard of care'" (Doc. 230-18, p. 5). 11 Speculation as to what may have occurred if Ms. Zak's case were presented to a MDTB (Opp., p. 14) is irrelevant.¹² The 2018 article plaintiff relies on from European Review is not admissible as evidence in chief and does not establish the standard of care in March 2017. The article by its own terms is also inapplicable to trained interventional radiologists like Dr. Sofocleous. 13

B) Plaintiff failed to provide expert testimony that Dr. Kemeny departed from the standard of care by not offering immunotherapy in March 2017.

Plaintiff's opposition contains only his attorney's statements regarding this claim.¹⁴

Plaintiff completely ignored the fact that Pembro was not FDA approved in March/April 2017

¹⁰ See 56.1 ¶68 and ¶70 (Plaintiff ignored Dr. Navuluri's opinions and fabricated testimony that does not exist).

¹¹ Drs. DeMatteo and Mayo agreed MDTB "not mandatory." See 56.1, ¶68 and ¶74 (did not controvert testimony).

¹² <u>See Rosales v. Fischer</u>, No. 07 Civ. 10554(LAP), 2011 WL 253392, *9 (S.D.N.Y. Jan. 24, 2011) ("speculation is insufficient to create a genuine issue of material fact").

¹³ <u>See</u> Doc. 237-17, p. 2 (the article is "to assist not only residents and fellows who are training interventional radiology but also practicing colleagues who are approaching this locoregional treatment."); and 56.1, ¶48.

¹⁴ <u>See Opp., p. 15; see also 56.1, ¶84; ¶86; ¶87 and ¶208.</u>

for treatment, or that Dr. Kemeny had no reasonable expectation that Ms. Zak would have benefited from the then experimental use.¹⁵ Ms. Zak's response to Pembro when started in October 2017, after both the treatment at issue and after the drug was approved by the FDA, is not relevant to decision-making in March 2017. Plaintiff's claim must be dismissed.

C) <u>Plaintiff failed to provide expert testimony that Dr. Sofocleous' decision to proceed</u> with ablation was a departure from the standard of care.

Plaintiff contends his experts refute Dr. Sofocleous' decision to proceed with ablation while relying on opinions from Dr. DeMatteo, Dr. Coakley and Dr. Israel (Opp., Footnote ("n.") 51) all of which are not admissible. The procedure at issue – a PET/CT-guided percutaneous ablation using a NeuWave machine – was recommended and performed by an interventional radiologist. (56.1, ¶135 and ¶48). Plaintiff's expert, Dr. DeMatteo, is a liver surgeon who performs surgical ablations, a medical specialty and procedure unrelated to Plaintiff's claims. The relevant fields of medicine are outside his area of expertise: namely, radiology and interventional radiology ("IR"). DeMatteo admitted that he is not an expert in IR and does not perform percutaneous ablations, and that he is not an expert in the field of radiology. Moreover, Dr. DeMatteo could not offer testimony as to the standard of care or any guidelines for percutaneous ablations. Ex. GG, T.277:4-14. Dr. DeMatteo conceded that an interventional radiologist may have a different perspective than a surgeon regarding this case. Id., T.276:13-

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¹⁵ <u>See</u> 56.1, ¶84 (Plaintiff violated Local Rule 56.1 by claiming the NCCN guidelines specifically recommend Pembro as a primary therapy option as there is no such statement contained therein). <u>See</u> Doc. 237-37. <u>See also</u> 56.1, ¶85; ¶86 and ¶87 (Plaintiff did not controvert the facts stated).

¹⁶ See Nimely v. City of New York, 414 F.3d 381, 399 n. 13 (2d Cir. 2005) ("[I]t is worth emphasizing that, because a witness qualifies as an expert with respect to certain matters or areas of knowledge, it by no means follows that he or she is qualified to express expert opinions as to other fields.").

¹⁷ <u>See</u> Second Declaration of Betsy D. Baydala ("Sec. Dec."), Exhibit ("Ex.") GG, T.232:18-233:6; T.243:12-13; <u>see also</u> 56.1, ¶¶38-39 (did not controvert facts). Dr. DeMatteo has no training and is not board certified in IR. Ex. GG, T.237:9-14. He does not receive the Journal of Vascular and IR or other radiologic journals; he does not attend conferences for radiology or IR. <u>Id.</u>, T.238:25-239:13. He uses a different ablation machine and does not utilize a PET-CT scan during surgical ablations. <u>Id.</u>, T.101:11-19; T.120:18-121:5 and T.238:21-24. Dr. DeMatteo has no training in radiology and does not formally review radiology studies and issue a report. <u>Id.</u>, T.236:20-237:8.

277:2.¹⁸ Dr. DeMatteo also testified it is the responsibility of the interventional radiologist performing the ablation to interpret the films. <u>Id.</u>, T.147:6-12. On the crucial issue of the proximity of Ms. Zak's lesion to structures in her liver, Dr. DeMatteo testified that a radiologist would be the appropriate specialist "to confirm ... the exact relationship. **From my point of view as a non-radiologist, that would be important**." Dr. DeMatteo is not qualified "by knowledge, skill, experience, training or education" to render expert opinions under FRE 702 on the issues of the radiologic distances from a lesion to structures in the liver or the standard of care applicable to interventional radiologists performing percutaneous ablations; Dr. DeMatteo's opinions are therefore not admissible and must be disregarded. ²⁰ The untimely "rebuttal" expert disclosures and opinions of Drs. Coakley and Israel are also not admissible. ²¹

Plaintiff's only expert on this issue is Dr. Navuluri, who offered no expert testimony that Dr. Sofocleous departed from the standard of care in proceeding with the ablation. The testimony plaintiff relies on only concerns alternatives relating to the informed consent process.²² Dr. Navuluri explicitly opined in his report that "the decision to use ablation is not outside the standard of care" (Doc. 237-35, p. 7), and he testified as to his reasoning "in part because of the added precision of the PET/CT modality" (Doc. 230-19, p. 8 (T.86:12-17). Dr. Navuluri directly contradicted Plaintiff's contention that this opinion was only "generally speaking":

Q: When you said the decision to use ablation is not outside the standard of care, you were not taking about this case, is that what you're saying?

¹⁸ He admitted there may have been developments in the field of IR that he was not aware of. Id., T.239:14-17.

¹⁹ <u>Id.</u>, T.99:15-100:1 (emphasis supplied); 56.1, ¶73 (Plaintiff did not controvert fact).

²⁰ See Alford v. United States, No. 17 Civ. 5217 (JFK), 2020 WL 376749, *16 (S.D.N.Y. Jan. 23, 2020) (slip copy) (expert in internal medicine unqualified to render opinions in other relevant fields related to medical issue: oncology, nephrology and urology); Foley v. United States, 294 F.Supp.3d 83, 92 (W.D.N.Y. 2018) (expert emergency medicine physician unqualified to opine on the appropriate standard practice for diagnosing and treating infection); Simpson v. Edghill, 169 A.D.3d 737, 739, 93 N.Y.S.3d 399, 402 (2d Dept. 2019) (expert "failed to articulate" any training in the treatment at issue or what he did to familiarize himself with the standard of care).

²¹ <u>See</u> Doc. 171 (Defendants' pre-motion letter to exclude the four rebuttal experts) and Doc. 174 (denied motion without prejudice to renewal). Defendants' request to file a separate motion to strike was denied. (Doc. 239).

²² See 56.1, ¶105-106 (Plaintiff fabricated testimony of Dr. Navuluri).

A: No. **I'm saying that in this case**, if the patient declined all other treatments and wanted an ablation knowing the risks involved and declined hypothetically a different chemotherapy agent, radiation treatment, surgery, whatever it might be, external beam radiation, if they were set on this, **I don't think it would be inappropriate or wrong of a physician to offer it**, as long as all the parties are aware of the risks that are involved. So I don't think that it's – again, I wouldn't recommend it, and I think that I would tell the patient that this is not something that I would do or recommend. **So ablation can be offered, it's within the standard of care**, but I don't think in this location it would be an appropriate thing to do.

(Doc. 237-11, T.189:25-190:25). Dr. Navuluri further testified that *he* does not have access to PET/CT scan when *he* performs percutaneous ablations that indisputably allows for "remarkably precise targeting of the lesion", and *he* would have performed a different procedure.²³ Dr. Navuluri's personal preference testimony is the exact type of expert testimony the Court has found insufficient to create an issue of fact.²⁴

D) <u>Plaintiff failed to provide expert testimony that Dr. Sofocleous breached the standard of care in performing the ablation.</u>

Plaintiff's expert, Dr. Navuluri, did not opine on the appropriate standard of care for the manner in which an interventional radiologist should perform an ablation, other than to create an ablation margin of at least 1 cm around the tumor. (56.1, ¶136). There is no dispute there was a complication and the ablation resulted in a larger than anticipated ablation zone; however, Plaintiff was required to establish through expert opinion that the larger than anticipated ablation zone was the result of a departure from the standard of care.²⁵ Dr. Navuluri attributed the larger ablation zone to "longer than typical ablation times and higher than usual ablation energies" as well as "more than one ablation and using two probes rather than one." However, Dr. Navuluri set forth neither the standard of care concerning the number of probes nor the appropriate

²³ See Sec. Dec. Ex. HH, T.73:7-19 and T.89:19-90:16; and 56.1, ¶104.

²⁴ See Zeak v. U.S., No. 11 Civ. 4253 (KPF), 2014 WL 5324319, *10 (S.D.N.Y. Oct. 20, 2014) (holding that an expert testifying as to "what I would do under the given circumstances" fails to provide evidence that the defendant's decision deviated from the standard of care).

²⁵ See Nestorowich, 97 N.Y.2d at 398, 767 N.E.2d at 671 ("Not every instance of failed treatment or diagnosis may be attributed to a doctor's failure to exercise due care."); see also 56.1, ¶152.

amount of time and energy to be used during an ablation.²⁶ Dr. Navuluri considered the use of multiple probes "aggressive", but this is a conclusory statement and silent as to the standard of care. Dr. Sofocleous used two probes to bracket the tumor and limit the chance of spreading the tumor, and Plaintiff did not negate that many interventional radiologists do so. (56.1, ¶¶137-139). There is also no dispute that Dr. Sofocleous employed a commonly used second run to ensure no cancer cells were left behind. (56.1, ¶141). Dr. Navuluri did not opine that the time and wattage settings used by Dr. Sofocleous were a departure from the standard of care.²⁷

Plaintiff's attorney argues that Dr. Sofocleous ignored Ethicon's suggestions regarding number of probes, wattage settings, and duration. (Opp., p. 10). Plaintiff's contentions ignore the actual Instructions for Use, as well as Dr. Sofocleous' and defense expert's testimony that the "Ethicon guidelines" are not followed because they are not replicable in a live organ." Indeed, it is undisputed that "physicians use their skill and experience to adjust these guidelines in a clinical setting." (56.1, ¶146). Plaintiff's attorney relies on "call home" data regarding a discrepancy between it and Dr. Sofocleous' procedure note. (Opp., p. 11). However, the Katrana Declaration and the "call home" data both lack foundation and constitute inadmissible hearsay evidence. The "call home" data is also an inadmissible "business record" as it is wholly unreliable. Plaintiff's expert, Dr. Navuluri, reviewed this data and testified that he had "not seen that type of data before." (Ex. HH, T.160:21-162:3). It is also undisputed that Dr. Sofocleous did

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²⁶ <u>See</u> 56.1, ¶151 (Plaintiff violated Local Rule 56.1 by his attorney statement that "portal vein thrombosis does not occur *sua sponte*, it is a complication that occurs when the ablation is attempted too close to the portal vein." The evidence cited does not support this claim. Dr. DeMatteo's opinions were silent on this issue, and Dr. Navuluri opined that "[a]ssumming no untoward complications from the procedure itself (biliary injury, portal vein occlusion, etc)" the ablation zone was "unnecessarily large." (Doc. 237-35, p. 8)). Plaintiff concedes that portal vein thrombosis is a known complication of ablations (56.1, ¶102) as opposed to a departure from care.

²⁷ Plaintiff attorney's statement that "the time and wattage used by Dr. Sofocleous was not within acceptable ranges" is not supported by the evidence cited. See 56.1, ¶148.

²⁸ <u>See</u> Doc. 237-13, p. 5 (the "Instructions for Use" allow for the use of multiple probes for liver tissue) and ("These examples are from ex-vivo animal (bovine) tissue. The size of ablation zones may vary in clinical settings due to vasculature structure and the cooling effect of blood flow not present in ex-vivo tissue."); 56.1 ¶146; and Sec. Dec., Ex. II, T.145:18-146:2 (not applicable because from dead livers).

not record the additional time of the second passes that ensured eradication of cancer cells (56.1, ¶¶141 and 143), which explains any discrepancy. After having reviewed both Dr. Sofocleous' procedure note and the "call home" data, Dr. Navuluri did <u>not</u> offer any opinion that Dr. Sofocleous' actions constituted a breach of the standard of care.²⁹ Plaintiff's remaining sensationalized arguments relating to "the magnitude of harm" caused by the ablation are irrelevant to the applicable standard of care. Having failed to establish that Dr. Sofocleous deviated from the standard of care during the ablation, summary judgment is proper.³⁰

POINT III: Plaintiff's wrongful death claim fails

Plaintiff contends "the ablation procedure alone caused Erika's liver failure." (Opp., p. 16). However, Plaintiff offered no expert testimony or other competent evidence to support this claim. Critically, Plaintiff did not controvert that Cleveland Clinic examined Ms. Zak's liver at the time of her death and its pathologist opined that Ms. Zak's explanted liver was "consistent with end stage liver disease (cirrhosis)" and "could be associated with chemotherapy induced liver injury and superimposed complications of cirrhosis" (56.1, ¶199). It is Plaintiff's burden to controvert this causation statement to a reasonable degree of medical certainty, and yet he completely ignores this critical evidence in opposition. Plaintiff merely acknowledges in the 56.1 Response that chemotherapy "could" have been associated with Ms. Zak's liver failure, but insufficiently claims her medical records, which pre-date this tissue exam and lack the conclusiveness of pathological findings, allegedly show the ablation caused her liver failure. <u>Id</u>.

²⁹ Plaintiff also did not dispute that when determining the appropriate amount of time and energy to apply, a physician can look to the medical literature (56.1 ¶144), and the medical literature (56.1 ¶145) is consistent with both Dr. Sofocleous' procedure note (56.1, ¶142) and the "call home" data as interpreted by Plaintiff's attorney.

³⁰ <u>See Zeak</u>, 2014 WL 5324319, *9 (holding plaintiff could not overcome the deficiency of the plaintiff's expert's inability to define the standard of care); <u>Foley</u>, 294 F.Supp.3d at 96 (dismissing malpractice claim where plaintiff's expert failed to explain any standard of practice).

However, these attorney statements without any expert opinion testimony are insufficient to refute (or rebut) the pathological findings of Ms. Zak's liver.³¹

Plaintiff's failure to controvert the Cleveland Clinic pathologist's opinion that Ms. Zak's liver failure was likely associated with chemotherapy, and Defendants' expert pathologist, Dr. Theise's, opinion that Ms. Zak's liver failure was due to the effects of chemotherapy toxicity is fatal to his claim. Plaintiff's meager attempt at refuting Dr. Theise's opinion based on "[t]he facts and the medical literature" (Opp., p. 20), reiterate the same insufficient arguments Plaintiff contained in his motion to preclude Dr. Theise, to which we respectfully refer the Court. (Doc. 234).³² The essential facts on this issue are undisputed³³ and uncontroverted.³⁴ Plaintiff's attorney's unsupported contention that there are no reported instances of cancer patients like Ms. Zak requiring a liver transplant (Opp., p. 21) is contrary to the undisputed testimony that Dr. Kemeny told Plaintiff in December 2017 that Cleveland Clinic was beginning to do transplants on patients with biliary sclerosis from pump treatment (56.1, ¶183).

Defendants' expert hepatologist, Dr. Bernstein, provide unopposed testimony that Ms. Zak's liver function tests recovered within weeks of the ablation, and she did not go into acute liver failure in April 2017.³⁵ He also opined in undisputed fashion that Ms. Zak developed progressive liver disease leading to fibrosis and cirrhosis months after the ablation due to multiple factors unrelated to the ablation including, her prior surgeries, the FUDR/HAI pump

³¹ Plaintiff's attorney makes numerous improper and unsupported statements in an effort to fill in the lack of expert testimony. <u>See</u> Opp., pp. 20-22.

³² <u>See</u> 56.1, ¶¶200-203 (Plaintiff failed to respond to the stated expert opinions of Dr. Theise and instead referred the Court to his motion to preclude; this is in violation of Local Rule 56.1 and these facts should be deemed admitted).

³³ See 56.1, ¶12, ¶17 and ¶¶190-191 (the HAI pump administered higher concentrations of FUDR chemotherapy directly to the liver with the side effect of liver toxicity); see also ¶¶18-23, ¶29, ¶44 and ¶54 (Ms. Zak received this treatment for over two years and required various dose reductions due to the impact on her liver function).

³⁴ <u>See</u> 56.1, ¶¶42-43 (Dr. Kemeny told Ms. Zak that the treatment could eventually hurt her liver and cause cirrhosis); <u>see also</u> ¶24 and ¶56 (ALK levels can be an indicator of bile duct injury and Ms. Zak's levels had increased by November 2016); <u>see also</u> 56.1, ¶59 and ¶61 (by December 2016, Ms. Zak was receiving Dexamethasone in her HAI pump to minimize biliary sclerosis).

³⁵ <u>See</u> 56.1, ¶¶156-159 (Plaintiff did not controvert Ms. Zak's ALT, AST and ALK levels). As set forth below, Plaintiff's reliance on Dr. Mayo's letter is insufficient to create an issue of fact. <u>See</u> 56.1, ¶160.

therapy, and different chemotherapies. (56.1, ¶182). Plaintiff failed to refute Dr. Bernstein's expert opinions. Dr. DeMatteo's speculation on this issue is inadmissible as he had no personal knowledge of Ms. Zak's health after May 2017 not having reviewed any of her subsequent medical records. Consequently, Dr. DeMatteo is not qualified to render an opinion on the cause of Ms. Zak's liver failure months after his last encounter with her and without the benefit of records or pathology. Dr. DeMatteo's testimony that "from the end of 2018 [1.5 years after the ablation] until her death in August 2019" the greatest threat to Ms. Zak's life was not her cancer (Doc. 237-8, T.130:8-18) is not a causal nexus between the ablation and liver failure.

Plaintiff cites to comments made by Dr. Mayo in September 2017 and December 2017 that Ms. Zak's "biggest challenge" and "main problem" was her biloma (Opp., n. 116-117). These comments make no mention of liver failure. Plaintiff cites to an alleged statement in a UNOS record with no known source of that information and is inadmissible hearsay. Plaintiff's reliance on a statement in Dr. Mayo's letter to United Healthcare from May 2018, which documents bile duct injuries due to the ablation, is created out of whole cloth as there is simply no statement therein that Ms. Zak developed "progressive liver failure and portal hypertension" due to the ablation. Notably, Plaintiff withheld key portions of Dr. Mayo's letter to the Court. Plaintiff made other mischaracterizations of the evidence to the Court:

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³⁶ <u>See</u> 56.1, ¶168 (did not controvert Dr. DeMatteo's testimony) and ¶187 (failed to note the specific records Dr. DeMatteo reviewed). <u>See</u> Doc. 237-3, p. 1 (Dr. DeMatteo only reviewed "Ms. Zak's March and April 2017 radiological films and her medical records" in forming his opinions).

³⁷ <u>See Major League Baseball Properties, Inc. v. Salvino, Inc.</u>, 542 F.3d 290, 311 (2d Cir. 2008) (expert opinions "without factual basis" and "based on speculation or conjecture" cannot be considered).

³⁸ Plaintiff's claim that Ms. Zak was not failing chemotherapy in March 2017 is contrary to the undisputed facts. See 56.1, ¶33, 45 and 62 (demonstrating third recurrence of metastatic cancer in one year); and ¶65.

³⁹ See Nealy v. U.S. Surgical Corp., 587 F.Supp.2d 579, 587 (S.D.N.Y. 2008) (holding medical consultant's letter

that did not state the required causal connection was not expert medical opinion evidence on the issue of causation).
⁴⁰ <u>Compare Opp.</u>, p. 17 <u>with Doc. 237-4</u>, p. 3 ("We have had her evaluated at our Multidisciplinary Liver Tumor Board multiple times over the past year and it [sic] effort to help address her progressive liver failure and portal hypertension."). Plaintiff also removed Dr. Mayo's statement "hepatic arteries had been embolized while she was in New York" (<u>compare Opp.</u>, p. 17 <u>with Doc. 237-4</u>, p. 2) as Dr. Mayo's statement was incorrect. <u>See</u> 56.1, ¶164.

- Plaintiff claims Dr. Kaufman "clarified" that in July 2017 "he embolized the proper hepatic artery *near the hepatic hilum*." (Opp., p. 19) (emphasis added). No such words were used. ⁴¹
- Plaintiff claims Dr. Kaufman noted Ms. Zak "has had patent hepatic artery for a while." (Opp., p. 19). However, Dr. Kaufman wrote "*I don't think* that she has had a patent hepatic artery for a while" as it was "chronically occluded" (Doc. 237-12, p. 6).⁴²
- Plaintiff states Dr. Pelley, an oncologist from Cleveland Clinic, corrected his June 2018 note that said "liver dysfunction is all secondary to complications of her chemotherapy and surgeries as well as her tumor" by signing a note on July 2, 2018 (Opp., p. 20); however, the note cited is from Dr. Harris, a palliative medicine physician who is unqualified to render an opinion on the cause of Ms. Zak's liver failure. (Doc. 237-4, pp. 23-24).

Plaintiff ignored Ms. Zak's subsequent treating doctors' testimony. Plaintiff would have the Court disregard Dr. Mayo's testimony that "[n]o, it's not fair to say that" the ablation irreparably damaged Ms. Zak's liver by noting she underwent subsequent treatment and stopping short of Dr. Mayo's full testimony: "So it's multifactorial and the entire scenario at this point can't really be attributed to one thing." (Doc. 230-13, T.42:15-43:10).⁴³ At his deposition, Plaintiff's attorney pressed Dr. Mayo on his opinions that refuted Plaintiff's claim:

- Q: Well, just so I'm clear, were there independent causes in your opinion for these various conditions or did they emanate from the initial injury sustained during the ablation?
- A: So patients that are in the situation that Erika was in she has received extensive treatment with hepatic arterial infusion, which is the pump treatment with an agent that also causes some bile duct injury in itself, okay, and has had other extensive treatments including lots of chemotherapy, she's had prior operations, et cetera, and all taken together that with this they all kind of form a multifactorial-like contribution to her ultimate outcome at this time. So it's really the culmination of everything that's happened to her over, you know, the treatment up to this point.

(<u>Id.</u>, T.43:11-44:2). The testimony Plaintiff relies on from Dr. Lopez relates to his December 27, 2017 note documenting the ablation causing a complication of "bile duct injury and biloma" with no mention of liver failure. (Doc. 237-4, T.64:14-19 and T.67:2-6). Plaintiff's arguments

⁴¹ <u>See</u> Doc. 237-12, p. 8 ("The coils are all distal to the HAI, so the embolization was the proper hepatic artery."). ⁴² <u>See also</u> 56.1, ¶60 (did not refute Dr. Sadler's expert opinion that there was significant diminution in the caliber of Ms. Zak's main hepatic arterial structures consistent with a chronic process such as FUDR pump effect).

⁴³ Contrary to Plaintiff's claim (Opp., n. 119), Dr. Mayo is an expert witness on causation. See Doc. 95 (Order).

regarding Ms. Zak's liver function tests and MELD scores, and that Ms. Zak was not in liver failure before the ablation are all irrelevant without expert testimony to establish a causal link between the ablation and the liver failure. Plaintiff failed to establish causation between the ablation and Ms. Zak's death entitling Defendants' to summary judgment on wrongful death.⁴⁴

POINT IV: Plaintiff's claim of lack of informed consent against Memorial fails

Plaintiff cites to case law that liability against a hospital may be found where it knew or should have known a physician acted without a patient's consent. These are not the facts here, where Ms. Zak signed a consent form on March 22, 2017 authorizing Dr. Sofocleous to perform the ablation at issue.⁴⁵ There is thus no evidence to support a claim that Memorial knew or should have known that Dr. Sofocleous allegedly acted without Ms. Zak's consent on April 10, 2017 (56.1, ¶210) entitling Memorial to summary judgment on this claim.⁴⁶

POINT V: Plaintiff's claim of lack of informed consent against Dr. Sofocleous fails It is undisputed the April 10, 2017 ablation was complicated by portal vein thrombosis and an injury to the bile duct. (56.1, ¶150, ¶161, ¶167 and ¶171). Plaintiff did not controvert the fact that on March 22, 2017, Dr. Sofocleous informed Ms. Zak of the risk of "injury to the bile duct." (56.1, ¶114). Plaintiff's argument that this disclosure was insufficient because of the total time "covering this risk" is belied by Dr. Navuluri's expert testimony that time is not determinative of the adequacy of the consent. (56.1, ¶128). Likewise, Plaintiff's attorney's

⁴⁴See Kennedy v. New York Presbyterian Hosp., No. 09 Civ. 6256 (RMB), 2011 WL 2847839, *4 (S.D.N.Y. Jul. 6, 2011) (holding without expert medical opinion supporting a plaintiff's theory of causation, "the Court must grant Defendants' motion."); Foley, 294 F.Supp.3d at 83 ("This crucial and unexplained gap in [plaintiff's expert's] analysis is fatal to Plaintiff's theory of causation.").

⁴⁵ <u>See</u> 56.1, ¶115 (no dispute Ms. Zak signed the consent form); and ¶132. The case law Plaintiff relies on affirms dismissal of this claim. <u>See Bailey v. Owens</u>, 17 A.D.3d 222, 223, 793 N.Y.S.2d 40 (1st Dept. 2005) (dismissing claim "where the consent form [plaintiff] signed clearly and distinctly authorized surgery" and "no evidence that the hospital knew or should have known that the surgeon may have been acting without plaintiff's informed consent.").

⁴⁶ Plaintiff cannot assert a cause of action against Dr. Kemeny as she did not perform the ablation. See Kushner v.

⁴⁶ Plaintiff cannot assert a cause of action against Dr. Kemeny as she did not perform the ablation. <u>See Kushner v. Schervier Nursing Care Center</u>, No. 05 Civ. 5297(DAB), 2011 WL 1201936, *6 (S.D.N.Y. Mar. 23, 2011) (dismissing lack of informed consent claim where the defendant did not violate the decedent's physical integrity).

⁴⁷ Plaintiff claims other ablation complications that Defendants refuted. <u>See</u> Doc. 229, Point II. Nonetheless, Plaintiff offered no expert testimony that any of these other alleged complications should have been warned of.

contention that Dr. Sofocleous "never bothered to explain what any of that meant" is insufficient without expert testimony in support thereof. There is also no evidence that Ms. Zak did not understand the risk of "injury to the bile duct." (56.1, ¶130). Indeed, the evidence demonstrates that prior to March 22, 2017, Dr. Sofocleous informed Ms. Zak of the risk of injury to the bile duct requiring drainage (56.1, ¶51 (Plaintiff did not controvert his own testimony)), such that upon Dr. Sofocleous informing Ms. Zak of "injury to the bile duct" on March 22, 2017, she immediately asked whether the lesion was near her bile duct. (Doc. 230-11, T.2:19-22). Plaintiff also did not controvert the fact that in response, Dr. Sofocleous twice informed Ms. Zak that one lesion was near the bile duct. (56.1, ¶121).

There is no expert opinion testimony that the standard of care required that Dr. Sofocleous warn Ms. Zak of the "specific risks of portal vein injury and thrombosis" as argued by his attorney in the 56.1 Response. (56.1, ¶118). Plaintiff's own expert conceded that if a physician considers a risk to be remote, the standard of care did not require that it be warned of specifically.⁴⁹ It is undisputed that Dr. Sofocleous considered the risk of portal vein thrombosis to be remote. (56.1, ¶117 and ¶134).

Plaintiff's attorney argues that "Dr. Sofocleous should have explained" the tumor being in "a dangerous location for ablation" and "extremely high" risk, such that "he failed to describe risks that reasonable physicians would have discussed." (Opp., p. 24). This is another attorney statement with no expert support. ⁵⁰ In addition, this argument relates to whether the ablation was contraindicated and Plaintiff is not entitled to again raise this claim cloaked as a different cause

⁴⁸ Plaintiff's attorney makes multiple inadmissible statements on this issue. <u>See</u> 56.1, ¶121. The layperson testimony of Ms. Metz regarding what risks should have been disclosed (Opp., p. 23) is inadmissible. <u>See Irish v. Tropical Emerald LLC</u>, No. 18-CV-82-PKC-SJB, 2021 WL 1827115,*6 (E.D.N.Y. May 6, 2021) (slip copy) ("[C]ourts routinely strike affidavits or declarations of witnesses who attempt to offer expert opinions as a lay fact witness").

⁴⁹ <u>See</u> 56.1, ¶118 (cited to testimony does not address specific risks Dr. Sofocleous should have allegedly discussed). ⁵⁰ <u>See</u> (Opp., ns. 163-164) (Plaintiff relies on Dr. Navuluri's testimony that he could not recall if arteries and veins were mentioned to Ms. Zak, and that the risk of bleeding does not encompass all injury to vessels; Dr. DeMatteo's report was silent as to what risks of ablation Dr. Sofocleous should have told Ms. Zak).

of action. 51 Plaintiff's reliance on Dr. Goldberg's testimony regarding Dr. Sofocleous' disclosure of "injury to liver" is also misplaced, 52 as are the various contentions regarding the consent visit note compared to the audio recording given the lack of expert testimony to establish any insufficiency of the disclosure.⁵³

It is undisputed that Dr. Sofocleous did not feel it necessary to disclose any alternatives to ablation. Contrary to Plaintiff's claim, this is not an admission that Dr. Sofocleous failed to act as a reasonable physician. New York law provides that Dr. Sofocleous was required to provide alternatives if a "reasonable medical practitioner under similar circumstances would have [so] disclosed." See N.Y. Pub. Health Law, §2805-d(1).54 Plaintiff's experts offered no such testimony. Plaintiff claims that "reasonable physicians have disagreed with [Dr. Sofocleous'] decision" not to disclose any alternatives, but the testimony Plaintiff cites to in support is unrelated. (Opp., p. 24). Defendants demonstrated that all alternatives were inferior to ablation. Indeed, Dr. Navuluri conceded that "ablation is the best (most effective) option after chemotherapy and surgical resection by NCCN guidelines."55 Plaintiff offered no expert testimony that either chemotherapy or surgery was a treatment option for Ms. Zak in March/April 2017.⁵⁶ Plaintiff also offered no expert testimony from a radiation oncologist that radiation was a viable treatment option.⁵⁷ Plaintiff's incorrect argument that his experts Dr.

⁵¹ See Naughright v. Weiss, 826 F.Supp.2d 676, 687 (S.D.N.Y. 2011) ("A claim for informed consent cannot arise out of mere allegations of negligence.").

⁵² Plaintiff did not (and cannot) cite to any testimony from Dr. Goldberg that disclosure of "injury to liver" was "inadequate." (Opp., p. 23). See 56.1, ¶115-116 (did not controvert the consent form lists "injury to liver" (56.1, ¶115), or that his expert Dr. Navuluri opined that the consent form did not violate the standard of care).

See Zeak, 2014 WL 5324319, *10 (holding no evidence the note deviated from the standard of care).

⁵⁴ Plaintiff's attorney's unsupported pronouncements regarding New York's informed consent statute, a patient's knowledge, and the risks/benefits August 2016 versus April 2017 (Opp., pp. 25-26) are inadmissible statements.

⁵⁵ See Doc. 230-19, p. 17 and 56.1, ¶83 (disregarded Dr. Navuluri's express opinion stated in his errata letter).

⁵⁶ Plaintiff's expert, Dr. DeMatteo, chose not to opine whether surgery was an option. See 56.1, ¶82; see also id., ¶78 (did not refute expert medical opinion of Dr. Rubinson that chemotherapy was inferior to ablation).

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Plaintiff did not dispute that radiation posed greater toxic effects to the liver compared to ablation. See 56.1, ¶91.

DeMatteo⁵⁸ and Dr. Navuluri "would have presented *any* other alternative" to ablation because of the "extreme risk associated with ablation" (Opp., p. 24) goes to whether the procedure was contraindicated, not what alternatives should be discussed.⁵⁹ Plaintiff's attorney states that "[m]ultiple viable alternatives were available that Dr. Sofocleous never disclosed to Erika." (Opp., p. 24). However, no expert testified that a reasonable interventional radiologist should have disclosed others.⁶⁰

With respect to the claim that radiation segmentectomy ("RS") should have been offered, the following facts are uncontroverted: there is no expert opinion that RS was a viable treatment option as "an angiogram would have to be performed to determine feasibility", ablation was more effective than RS in terms of eradicating cancer, and RS was not a standard of care treatment option. (56.1, ¶88-90). Fatal to Plaintiff's claim is the fact that there is no testimony from Dr. Navuluri that a reasonable interventional radiologist with the advantage of access to a PET-CT scan during ablation should have informed Ms. Zak of the alternative of RS.

Plaintiff failed to introduce any admissible evidence that a reasonable person in Ms. Zak's circumstances highly motivated to obtain a potential cure of the new lesions (56.1, ¶132) would have refused ablation, which she successfully underwent months earlier (<u>id.</u>, ¶52) and which offered her the best chance of success to eradicate her cancer (<u>id.</u>, ¶89). Dr. DeMatteo's testimony on this issue is pure speculation. Plaintiff's claim that Ms. Zak was seeking additional

⁵⁸ Dr. DeMatteo offered no opinions as to Dr. Sofocleous' disclosures and testified he could not comment on this issue (referred to as the "shared decision-making process"). <u>See</u> Ex. GG, T.148:20-151:14.

⁵⁹ The cited to testimony is not related to what Dr. Sofocleous should have disclosed. <u>See</u> Opp., n. 167. The claimed alternative of IRE is based on the argument that the ablation was allegedly contraindicated. <u>See</u> 56.1, ¶92. ⁶⁰ Plaintiff's arguments regarding Ms. Zak not being "evaluated" for treatment/procedures not performed by Dr. Sofocleous, an interventional radiologist, such as surgery, radiation, immunotherapy and chemotherapy, are irrelevant to the sufficiency of Dr. Sofocleous' consent discussion for ablation.

chemotherapy options in March/April 2017 is directly refuted by the evidence.⁶¹ Plaintiff failed to establish a prima facie showing necessary for a lack of informed consent claim.⁶²

<u>POINT VI</u>: <u>If any claims survive</u>, <u>Plaintiff cannot recover certain damages sought</u> ⁶³ A) Plaintiff failed to satisfy his burden of proof for past and future lost earnings: Ms.

Zak left the work force in 2014 after she was diagnosed with Stage IV cancer and she did not return to the work force. (56.1, ¶8 and ¶212). Plaintiff offered no expert opinion testimony that Ms. Zak was cured of her Stage IV cancer or that she could have returned to a normal life, including work.⁶⁴ This glaring absence of proof is fatal to any claim for these damages. Plaintiff's contention that he could make an "at least plausible" argument is unavailing as it is not the relevant legal standard. How long Ms. Zak likely would have lived "cancer free" had she survived the liver transplant surgery was never established. Additionally, Plaintiff's attorney's bare statements, such as the "odds were in her favor", are insufficient to prove these damages.

- B) <u>Plaintiff failed to satisfy his burden of proof of loss of household services</u>: Plaintiff cannot prove that Ms. Zak handled "most of the household services as needed" with a conclusory statement that is not supported and disputed by the evidence showing the impact of her cancer. ⁶⁵
- C) <u>Plaintiff offered no proof of funeral/burial expenses</u>: Plaintiff only testified he did not know the total amount of funeral expenses. Plaintiff's Declaration (Doc. 237-15) is inadmissible hearsay with no proof of actual expenses paid by him.

⁶¹ See 56.1, ¶25, ¶28; ¶77 (did not controvert testimony that Ms. Zak "was very tired of doing chemo.") and ¶123.

⁶² See Orphan v. Pilnik, 15 N.Y.3d 907, 908-909, 914 N.Y.S.2d 729 (N.Y. 2010) (no issue of fact where plaintiff's expert "would not state with certainty that the information plaintiff allegedly received ... was a departure from what a reasonable practitioner would have disclosed"); Hylick v. Halweil, 112 A.D.2d 400, 401, 492 N.Y.S.2d 57, 59 (2d Dept. 1985) (bare assertions by an expert that it was "standard practice" to advise a patient "of risks, benefits and alternatives" is insufficient to constitute a prima facie showing of qualitative insufficiency of consent).

⁶³ Plaintiff essentially concedes he cannot seek recovery for certain damages he pled (e.g., loss of consortium for child, loss of guidance for spouse, pre-judgment interest for the non-death claims). (Opp., pp. 27-29).

⁶⁴ Plaintiff's claim that Ms. Zak had "no detectible cancer in her <u>body</u>" is unsupported by Dr. Theise's testimony that there was no detectible cancer in her <u>liver</u>. <u>Compare</u> 56.1, ¶116 <u>with</u> (Doc. 237-16, T.60:23-61:17). <u>See also</u> 56.1, ¶205 (did not refute Dr. Lopez's testimony); and ¶206 (did not refute Dr. Mayo's testimony).

⁶⁵ See 56.1, ¶8, ¶18, ¶28, ¶31, ¶33, ¶37, ¶45, ¶52, ¶62 and ¶132.

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